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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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| In Re: Application of PETER NASH ET AL | ) | |
| Serial No.: 10/039,977 | ) | |
| Filed: January 8, 2002 | ) | Group Art Unit 1644 |
| For: IMMUNOGEN ADHERENCE INHIBITOR AND METHOD OF MAKING AND USING SAME | ) | Exr. P. Huynh |
| Case Docket No.: C150.12.3E | ) | |

**APPELLANTS' BRIEF UNDER 37 CFR 1.192**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is in support of an appeal to the Board of Appeals from the final rejection dated July 28, 2004 of Claims 1 to 19. Copies of Claims 1, 3 and 5 to 18 are attached Appendix A.

## 1. REAL PARTY IN INTEREST

The real party in interest is Camas Incorporated, a Minnesota corporation having a place of business at 260 Derrynane Street, Le Center, Minnesota 56057, assignee of the invention and application.

## 2. RELATED APPEALS AND INTERFERENCES

U.S. Application Serial No. 09/616,843, parent application and related applications Serial Nos. 10/025,567 and 10/038,260 are pending before the Board of Appeals and Interferences.

PCT Application No. US/01/49588 is a related application

## 3. STATUS OF CLAIMS

Claims 1, 3 and 5 to 18 are pending in the application.

Claims 1, 3, 17 and 18 have been rejected under 35 USC 112.

Claims 1, 3 and 5 to 18 have been rejected under 35 USC 103(a).

No claims have been allowed.

## 4. STATUS OF AMENDMENTS FILED SUBSEQUENT TO FINAL REJECTION

An Amendment 37 CFR 1.116 was filed on December 8, 2004. No response has been received.

## 5. CONCISE SUMMARY OF THE INVENTION

The invention is a method of substantially reducing or eliminating the incidence of illnesses in humans caused by the presence of targeted colony-forming illness-causing immunogens in meat by inhibiting the ability of the immunogens from adhering to the rumen or intestinal tracks of food animals. The targeted colony-forming illness-causing immunogens are from a class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. These immunogens are common bacterial immunogens which cause food borne illness in humans and produce flu-like symptoms such as nausea, vomiting, diarrhea and fever, and in some cases kidney damage or death. *Page 2, lines 8-10.* The method is not a treatment for an illness in humans. The method is used to prevent illness in humans.

The principal object of the method is to substantially prevent the adherence of immunogens, such as *E. coli* O157:H7 from colonizing and growing in the rumen or intestinal tracts of food animals and substantially eliminate the immunogen from the feces of the animals. *Page 3, lines 1-5.* Foodstuffs contaminated with these bacteria have caused gastro-intestinal distress in hundreds of thousands of humans and the recall and destruction of millions of pounds of food. *Page 2, lines 10-17.*

The young chickens receive passive antibody protection through the store of antibodies placed in the eggs in which they develop from the embryonic stage. Chickens, in particular, have the ability to "load up" their eggs as they are formed, with a very large supply of antibodies concentrated many fold over that which is present in the serum of the hen. In addition, chicken antibodies are much more stable and resistant to inactivation through digestion than mammalian antibodies, especially under adverse conditions. Once immunized the hen layers the unique IgY type immunoglobulins in the yolk while depositing the common chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. Furthermore, the large quantities of an antibody which is placed in eggs are much more exclusively those specific for the antigen to which the mother has most recently been exposed to and challenged by. This all results in the eggs of chickens being a most ideal source for large quantities of economically produced, highly specific and stable antibodies.

The method for reducing or eliminating the incidence of illness in humans by inhibiting the ability of immunogens to adhere to the rumen or intestinal tracts of food animals thereby reducing the ability of the immunogens to multiply comprises first inoculating female chickens, in or about to reach their egg laying age, with the particular targeted immunogen from a class of immunogens consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. Then, after a period of time sufficient to permit the production in the bird of antibody to the targeted immunogen, the eggs laid by the birds are harvested. The entire antibody-containing contents, yolk and albumin, of the eggs are separated from the shells and dried to provide a dried antibody product. The dried separated egg antibody adherence inhibiting product may be stored or shipped for use when needed. The dried egg antibody product incorporating the antibody specific to the targeted immunogen is administered to the food animals by distributing the antibody material

substantially uniformly throughout an animal feed or water and then supplying the resulting antibody-containing animal feed to the food animals. The antibody-containing animal feed is supplied to food animals during the normal finishing schedule prior to slaughter. The IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen. The IgY immunoglobulins binding to illness-causing immunogens is assisted by the IgM and IgA immunoglobulins. The specification states that the IgY immunoglobulins very tightly bind to, coat, cover and obliterate adherins which attached themselves to their hosts. *Page 12, lines 11-13.* The particular language is the "binding of IgY immunogens to protein-wasting immunogens is being increased by the IgM and IgA immunoglobulins." This function is supported by the disclosure that the hen layers the unique IgY type immunoglobulins in the yolk while depositing the chicken IgM and IgA immunoglobulins in the albumin. The albumin helps resistance to the whole egg preparations and helps protect the avian antibodies. *Page 10, lines 4-5.* The whole egg preparation includes the IgY immunoglobulins in the yolk and IgM and IgA immunoglobulins in the albumin. The term "helps" means aids, assists and encourages the protection of the avian antibodies. This language supports the increase in the binding of IgY immunogens to the illness-causing immunogens as more IgY immunogens are available to bind to the illness-causing immunogens. The albumin IgM and IgA immunoglobulins increase binding in the mucus tissue of the digestive tract of the antibody containing material thereby providing a longer sustaining effect of the antibody containing material. The result is the use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the digestive tracts of the animals. The IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen. The binding process is assisted by the IgY and IgA immunoglobulins by providing a longer sustaining effect of the antibody product. The IgM and IgA immunoglobulins have di-sulfide bonds that retain

molecules together and provide larger antibody containing molecules. The larger antibody containing molecules are more effective in preventing adherence of the targeted immunogen in the digestive tract of the animal. Albumin is a protein that protects the activity of the IgY type immunoglobulin thereby increasing its active life in the intestinal tract. The result is that use of the antibody whole egg, yolk and albumin, mixed with animal feed or water substantially prevents adherence of the targeted immunogen in the intestinal tract of the animal thereby preventing multiplication and colonizing of the immunogen in the intestinal tract of the animal. Contamination of animal products and meat is eliminated due to the absence of the immunogen in the feed lot and its contents.

Appellants have discovered that egg IgY immunoglobulins must bind to protein-wasting immunogens to inhibit adherence of the immunogens in the intestinal tracts of animals. The totality of the teachings of the prior art do not reveal this discovery and advantageous results.

Appellants have conducted bead studies to demonstrate that antibodies disclosed in the application bind to bacteria. Bead studies were used because they can be seen more clearly. The beads are activated and then coated with antibodies from specific egg products disclosed in the application. The binding action of egg immunoglobulins is illustrated in Exhibits A to D of record. The binding action of the egg immunoglobulins to applicants' claimed method for reducing or eliminating the incidence of illnesses in humans is a discovery beyond the teachings of the prior art.

An alternate embodiment of the method includes the coating of carrier material with the combined egg yolk and albumin. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard animal feeds. *Example 21, pages 23 and 24.* The feed mixed with the carrier material coated with entire contents of the

eggs is supplied to the animals. The yolk and albumin immunoglobulins bind the protein-wasting immunogens on the mucus tissue of the rumen and digestive tract of the animal thereby prevent adherence of the protein-wasting immunogen in the intestinal tract of the animal. The coated carrier material increases the duration of the effectiveness of the immunoglobulins.

A further alternate embodiment of the method includes the use of coating the mixed entire yolk and albumin on dry carrier material. A separate drying process is not used prior to coating of the carrier material with the egg yolk and albumin. The elimination of a separate drying step increases the effectiveness of the immunoglobulins in inhibiting adherence immunogens in the intestinal tracts of animals.

## 6. CONCISE STATEMENT OF ALL ISSUES PRESENTED FOR REVIEW

A. Do Claims 1, 3, 17 and 18 comply with the requirements of 35 USC 112 as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

B. Whether Claims 1, 2, 5 and 11 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Kaspers et al, Sugita-Konishi et al*, U.S. Patent No. 6,086,878 (*Adalsteinsson et al*) and U.S. Patent No. 5,741,489 (*Pimental*).

C. Whether Claims 2 and 8 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Kaspers et al, Sugita-Konishi et al*, U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 5,741,489 (*Pimental*) and *Pell et al.*

D. Whether Claims 2 and 14 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Kaspers et al, Sugita-Konishi et al*, U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 5,741,489 (*Pimental*) and *Adesiyum et al.*

E. Whether Claims 3, 4, 6, 7, 12, 13 and 17 to 19 are unpatentable under 35 USC

103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Kaspers et al, Sugita-Konishi et al*, U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 5,741,489 (*Pimental*), and U.S. Patent No. 4,166,867 (*Betz et al*).

F. Whether Claims 8 to 10 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Kaspers et al,* U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 5,741,489 (*Pimental*) and U.S. Patent No. 4,166,867 (*Betz et al*).

G. Whether Claims 14 to 16 are unpatentable under 35 USC 103(a) over U.S. Patent No. 5,080,895 (*Tokoro*) in view of *Adesiyum et al, Kaspers et al,* U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 5,741,489 (*Pimental*) and U.S. Patent No. 4,166,867 (*Betz et al*).

## 7. GROUPING OF CLAIMS

The claims fall into three (3) groups. The separate groups of claims do not stand or fall together.

Group I comprises Claims 1, 5, 8, 11 and 14. These claims define Appellants' method for reducing or eliminating the incidence of illnesses in humans caused by colony-forming illness-causing immunogens in meat. The illness-causing immunogens are from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter*. The method includes drying of the entire contents of eggs having yolks with IgY immunoglobulins and albumin with IgM and IgA immunoglobulins. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals inhibit multiplication and colonization of the illness-causing immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the colony-forming illness-causing immunogens which inhibit the ability of the colony-forming illness-causing immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the

IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the illness-causing immunogens. The result is the colony-forming illness-causing immunogens cannot multiply or colonize in the intestinal tract of the animal thereby reducing or eliminating the incidence of illness in humans caused by the illness-causing immunogens from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

Group II comprises Claims 3, 6, 7, 9, 10, 12, 13, 15 and 16. These claims include the subject matter of parent Claims 5, 8, 11 and 14 and the process of drying the entire contents of the eggs having yolk IgY and albumin IgM and IgA immunoglobulins by coating dry feed carrier material with the entire contents of the eggs. The dry feed carrier material is from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beat pulp. The coated carrier material increases the duration of the effectiveness of the IgY immunoglobulins and facilitates mixing with standard animal feeds.

Group III comprises Claims 17, 18 and 19. These claims define a method for reducing or eliminating the incidence of illnesses in humans caused by a colony-forming illness-causing immunogen in the rumen or intestinal tracts of food animals by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of animals and reduce the ability of the immunogen to multiply. The immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. The method includes providing a feed carrier material, coating the feed carrier material with the antibody yolk and albumin of the harvested eggs. The carrier material coated with the antibody yolk and albumin is distributed substantially uniform in animal feed. The entire contents of the eggs having the IgY immunoglobulins and IgM and IgA immunoglobulins administered to the food animals reduce or eliminate the incidence of illnesses in humans caused by the presence of colony-forming illness-causing immunogens in the intestinal tracts of the animals. The IgY immunoglobulins bind to the colony-forming illness-

causing immunogens which inhibits the ability of the colony-forming illness-causing immunogens to adhere to the intestinal tracts of the animals. The binding process is assisted and helped by the IgM and IgA immunoglobulins. In other words, the IgM and IgA immunoglobulins increase the binding of IgY immunoglobulins to the protein-wasting immunogens. The method does not include a separate step of drying the antibody yolk and albumin as required by the method of Claims 3, 6, 7, 9, 10, 12, 13, 15 and 16.

## 8. ARGUMENT

### A. Rejection of Claims 1, 3, 17 and 18 under 35 USC 112

Claims 1, 3 and 17 have been amended to define Appellants' method for reducing or eliminating the incidence of illnesses in humans caused by the presence of targeted colony-forming illness-causing immunogens from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. Claim 18 depends on Claim 17 and includes the elements of Claim 17. This amendment overcomes the rejection of these claims under 35 USC 112 as containing subject matter which was not described in the specification. As noted by the examiner, the specification discloses a method of reducing or eliminating the incidence of food borne illness in humans caused by the presence of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter* by inhibiting the ability of these colony-forming immunogens to adhere to the rumen or intestinal tracts of food animals thereby reducing the ability of the immunogens to multiply and colonize in the rumen or intestinal tracts of the food animals. *Office Action 7/28/04 ¶ 4, lines 10-13 and lines 60-63.*

Claims 2, 4 and 19 define the illness-causing immunogen selected from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. These claims were not rejected under 35 USC 112. In view of the amendments to Claims 1, 3 and 17, the rejection under 35 USC 112 must be withdrawn.

Under 35 USC 112 ¶ 1 "[t]he specification shall contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor to carry out his invention."

The specification clearly discloses Appellants' method for reducing the incidence of food borne illnesses caused by the presence of colony-forming illness-causing immunogens in the rumen or intestinal tracts of food animals. The Examiner has acknowledged that the specification discloses applicants' method reducing the incidence of food borne illnesses in humans.

The Examiner has erroneously construed the requirements of 35 USC 112 to include any person skilled in the art to make and use the invention commensurate in scope with the claims. This is not the requirement of 35 USC 112 ¶ 1. To the contrary, it is the specification, according to 35 USC 112 ¶ 1, that contains the written description to enable a person skilled in the art to make and use the same. The claims particularly point out and distinctly claim the subject matter of the invention.

Appellants have provided a representative number of species of colony-forming illness-causing immunogens to describe the genus identified by the terms target colony-forming illness-causing immunogens in meat. These immunogens are well known illness-causing immunogens. The species of immunogens are identified as from a class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. This class is sufficient to identify the genus of like immunogens to a person skilled in the art. One skilled in the art would be aware of the bacterial antigens noted by *Stolle et al '018* in column 5, lines 5-35. Claims 1, 3 and 17 particularly point out and distinctly claim the subject matter of applicants' method of reducing or eliminating the incidence

of illnesses in humans as described in the specification with respect to *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

**B. Rejection of Claims under 35 USC 103(a)**

§ 103 Conditions for patentability; nonobvious subject matter

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person have ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 USC 103(a).

The test for determining obviousness of a claimed invention under 35 USC 103(a) is a four-part inquiring comprising (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) commercial considerations when such evidence is present. *Graham v. John Deere Co.*, 383 US 1 (1966); *Simmons Fastener Corp. v. Illinois Tool Works*, 222 USPQ 744 (Fed. Cir. 1984).

Obviousness cannot be properly established by locating references which describe various aspects of a patent applicant's invention without also showing evidence of a motivating force which would impel one skilled in the art to do what the patent applicant has done. Simply because one can reconstruct an invention by combining isolated teachings of references is not a basis for an obviousness conclusion unless sufficient impetus can be shown which would have led one skilled in the art to combine the teachings to make the claimed invention. *Ex Parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. 1993).

The Federal Circuit has also made it clear that the showing of a motivation to combine two or more references must be "clear and particular". See for example *Winner International Royalty Corp.*

*v. Wang*, 53 USPQ2d 1580, 202 F.3d 1340 (Fed. Cir. 2000), where the Federal Circuit stated:

> When an obviousness determination is based on multiple references, there must be a showing of some "teaching, suggestion, or reason" to combine references. [Citation omitted].
> Although a reference need not expressly teach that the disclosure contained therein should be combined with another, [citation omitted] the showing of combinability, in whatever form, must nevertheless be "clear and particular."

As the Federal Circuit also stated:

> "The factual inquiry whether to combine references must be thorough and searching" Id. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.

*In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002).

It is well established that in deciding that a novel combination would have been obvious, there must be supporting teaching in the prior art. *In re Newell*, 13 USPQ2D 1248 (Fed. Cir. 1989). The prior are must provide a suggestion to make the combination with structure shown and claimed. *CR Bard Inc. v. M3 Systems, Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998).

The Examiner has the burden under Section 103 to establish a *prima facie* case of obviousness. He can satisfy this burden *only* by showing some objective, clear and particular teachings in the prior art of that knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references. *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

It is submitted that the prior art of record does not contain a clear and particular motivation to combine these references.

The primary reference in all of the rejections based upon 35 U.S.C. 103(a) is U.S. Patent No. 5,080,895 (*Tokoro '895*)

*Tokoro '895* discloses a method of inhibiting diarrhea in animals with bird antibody IgY using the yolks, albumin and the yolks of eggs. This method is related to the use of raw eggs by

cattle herdspersons to treat scours (diarrhea in cattle caused by intestinal infection). *Tokoro '895* is directed to a specific antibody containing substance from eggs and method of production and use thereof for the prevention and treatment of colibacillosis and diarrhea in animals. There is no disclosure in *Tokoro '895* of an IgY immunoglobulin that binds to colony-forming illness-causing immunogens. The antibody containing substance also is used as a nutrition supplement, and as an additive to food animals. *Tokoro '895* does not provide a teaching of a method for reducing or eliminating the incidence of illnesses caused by colony-forming illness-causing immunogens by binding egg IgY immunoglobulins combined with IgM and IgA immunoglobulins to illness-causing immunogens, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*, to inhibit the ability of these immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply and colonize.

*Tokoro '895* does not coat a dry feed carrier with a mixed egg yolk and albumin product.

The object of the *Tokoro '895* disclosure is to administer to animals affected by an intestinal infection disease for therapeutic purposes. *Column 4, lines 1-4.* The *Tokoro '895* substance is also useful in the treatment of various infectious diseases, additives in food for livestock, cosmetics and medicines. *Column 4, lines 16-21.* Appellants' claimed method is not a treatment of a disease in animals. Appellants' method is the prevention of illnesses in humans by eliminating the illness-causing immunogens in animal meat. Appellants have discovered a new and useful method of preventing, as opposed to treating, illnesses in humans caused by a colony-forming illness-causing immunogen from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

The Examiner has acknowledged that the teachings of *Tokoro '895* do not include "the method wherein the antibody in the eggs including IgY immunoglobulins in the yolks of the eggs whereby the IgY immunoglobulins bind to a targeted colony-forming illness-causing

immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted-colony forming illness-causing immunogen in the intestinal tract of the animals." *Office Action of July 28, 2004, page 7, lines 9-14.*

The *Kaspers et al* publication discloses the transfer of maternal antibodies into the egg of a chicken and subsequent transport thereof into a developing embryo. There is no disclosure in the *Kaspers et al* publication of IgY, IgM and IgA immunoglobulins whereby the IgY immunoglobulins bind to colony-forming or protein-wasting immunogens with the binding process being assisted by the IgM and IgA immunoglobulins thereby inhibiting the colony-forming or protein-wasting immunogens from adhering to the intestinal tracts of animals.

*Pimental '489* discloses a method for increasing feed conversion efficiency in mammals with a diet containing an antibody produced using he enzyme urease as the antigen. *Pimental '489* states that chicken antibodies are generally known to protect the recipient against bacterial infections.

*Sugita-Konishi et al* discloses a microbial adherence inhibitor that uses 26 different strains of bacteria in one chicken for immunogens. This is not the way to produce specific antigens. A specific IgY immunogen from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter* does not bind to the colony-forming illness-causing immunogens in a manner to inhibit the ability of the colony-forming illness-causing immunogen to adhere to the intestinal tracts of animals.

*Adalsteinsson et al* disclose a method of administering to animals an effective amount of a gastrointestinal neuro-modulator antibody to neutralize the neuro-modulator. There are no motivating directions or suggestions in *Adalsteinsson et al* that would impel one skilled in the art to produce the claimed method. There is no teaching of a method for reducing or eliminating the incidence of illnesses in humans by binding IgY immunoglobulins combined with IgM and IgA

immunoglobulins to a protein-wasting immunogen to inhibit the ability of the protein-wasting immunogen to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogen to multiply. The egg is dried into an egg powder. An example of drying is spray drying. The dried egg powder can be mixed with animal rations or sprayed directly onto food pellets preferably in oil. *Column 9, lines 31-39.* This is a mixing process wherein dry powder is mixed with animal rations which include food pellets. Appellants coat a carrier material with the entire contents of the harvested eggs or dried egg antibody product which inhibits adherence of a colony-forming illness-causing immunogen to the intestinal tracts of animals. This is not suggested by *Adalsteinsson et al.* The coated carrier material is distributed into the animal feed. The animal feed mixed with the coated carrier material is supplied to the animals. The carrier material is defined in Claims 7, 10, 13, 16 and 18 as a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grain and beet pulp.

*Pimental '489* is limited to the use of an antibody against the enzyme urease to obtain increased feed utilization and body weight gain in animals. There is no teaching in *Pimental '489* of a method for reducing or eliminating the illnesses in humans by binding IgY immunoglobulins combined with IgM and IgA immunoglobulins to protein-wasting immunogens from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter* to inhibit the ability of the protein-wasting immunogens to adhere to the rumen or intestinal tracts of food animals and to reduce the ability of the immunogens to multiply.

*Pell et al* discloses that pathogens (immunogens) such as *E. coli* 0157:H7, *Listeria* monocytogenes, and *Salmonella spp* are major problems for the swine and poultry industries and these microbes post potential threat to human health because many outbreaks have been traced to ground beef and some to raw milk in the case of *E. coli* (see page 2674, column 1, *E. coli* 0157:H7, in particular). *Pell et al* further teach that more core excreted *Listeria* monocytogenes

during winter than summer and human infections have been associated with consumption of unpasteurized diary products and healthy animals can be asymptomatic carriers (see page 2675, column 2, *Listeria* monocytogenes). *Pell et al* also teach that *Salmonella* typhi is the organism that is responsible for 45% of the food borne disease in which the gastroenteritis have been traced to foods of animal origin and the economic costs of salmonellosis have been estimated at close to $1 billion per year and that the problem has been exacerbated by increasing antimicrobial resistance among *Salmonella spp.* serotypes (see page 2676, column 1, *Salmonella spp*, in particular).

*Adesiyum et al* disclose that *Campyloacter* bacteria causes diarrhea in animals. Piglets have the highest prevalence of campylobacters infection, followed by calves and lowest in lambs (see abstract, in particular).

*Betz et al* disclose a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil to enhance palatability of horse feeds. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength to the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody. There is no suggestion in *Betz et al* of a coating of a carrier material with IgY antibody.

The separate and combined teachings of the second references, *Kaspers et al, Sugita-Konishi et al*, U.S. Patent No. 6,086,878 (*Adalsteinsson et al*), U.S. Patent No. 5,741,489 (*Pimental*), *Pell et al, Adesiyum et al* and U.S. Patent No. 4,166,867 (*Betz et al*) with *Tokoro*, do not suggest to one skilled in the art the binding of IgY immunoglobulins to illness-causing immunogens and that this binding is helped or assisted and increased by the IgY and IgA immunoglobulins. There is no clear and particular motivation for a person skilled in the art to

combine these references. Further, any combination of these references would not produce applicants' claimed method for reducing or eliminating the incidence of illness in humans caused by the presence of targeted colony-forming illness-causing immunogens from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

**C. Rejection of Claims 1, 2, 5 and 11 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al, Sugita-Konishi et al, Adalsteinsson et al '878* and *Pimental '489*.**

Apellants' analysis, *supra*, of the primary reference, *Tokoro '895*, and secondary references, *Kaspers et al, Sugita-Konishi et al, Adalsteinsson et al '878* and *Pimental '489* is applicable to this rejection.

Claim 2 has been cancelled. The subject matter of Claim 2 has been included in Claim 1.

Claim 5 defines Appellants' method for reducing or eliminating the incidence of illnesses in humans by the presence of only *E. coli*. The IgY immunoglobulins bind to the *E. coli* immunogen to inhibit adherence of the *E. coli* immunogen in the intestinal tract of food animals. This binding is assisted by the IgM and IgA immunoglobulins. The prior art does not limit the method to *E. coli* and the binding of the IgY immunoglobulins to the *E. coli* immunogen to inhibit adherence of the *E. coli* immunogen in the intestinal tract of food animals.

Claim 11 defines Appellants' method for reducing or eliminating the incidence of illnesses in humans caused by the presence of *Salmonella* immunogen in meat. The IgY immunoglobulins bind to the *Salmonella* immunogen to inhibit adherence of the *Salmonella* immunogen in the intestinal tract of food animals. This binding is assisted by the IgM and IgA immunoglobulins. The prior art does not limit the method to *Salmonella* and the binding of IgY immunoglobulins to the *Salmonella* immunogen to inhibit adherence of the *Salmonella* immunogen in the intestinal tract of food animals.

From the combined teachings of the references the claimed method as a whole would not

have been obvious at the time the invention was made to a person having ordinary skill in the art. The Examiner's combination of references is based upon a reasonable expectation of success of producing the claimed invention. The reasonable expectation of success is not the obvious requirement of 35 USC 103(a).

**D. Rejection of Claims 2 and 8 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al, Sugita-Konishi et al, Adalsteinsson et al '878, Pimental '489* and *Pell et al.***

Appellants' analysis, *supra*, of the primary reference *Tokoro '895*, and secondary references, *Kaspers et al, Sugita-Konishi et al, Adalsteinsson et al '878*, *Pimental '489* and *Pell et al*, is applicable to this rejection.

Claim 2 has been canceled. The subject matter of Claim 2 has been incorporated in Claim 1. The colony-forming illness-causing immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. The illness-causing immunogen defined in Claim 8 is *Listeria*. *Pell et al* is cited by the Examiner to show that it is known that *E. coli*, *Listeria*, and *Salmonella* are threats to human health. Appellants in paragraph 0004 of the specification identify common bacterial immunogens, *E. coli*, *Listeria*, *Salmonella* and *Campylobacter* which cause food borne illness in humans. *Pell et al* and the noted common bacterial immunogens are the problem which is alleviated by Appellants' method for reducing or eliminating the incidence of illnesses in humans caused by the presence of *Listeria*. *Pell et al* do not suggest a solution to this problem. The combined teachings of the references do not reveal that the claimed method as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

**E. Rejection of Claims 2 and 14 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al, Sugita-Konishi et al, Adalsteinsson et al '878, Pimental '489* and *Adesiyum et al***

Appellants' analysis, *supra*, of the primary reference, *Tokoro '895*, and secondary references, *Kaspers et al, Sugita-Konishi et al, Adalsteinsson et al '878, Pimental '489* and *Adesiyum et al*, is applicable to this rejection.

Claim 2 has been cancelled. The subject matter of Claim 2 has been incorporated in Claim 1. The colony-forming illness-causing immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*. The illness-causing immunogen defined in Claim 14 is *Campylobacter*. The fact that *Campylobacter* causes diarrhea in animals does not suggest Appellants' claimed method. The effects of *Camplyobacter* on animals is part of the problem which is alleviated by Appellants' claimed method. The recognition of a problem does not suggest a solution to the problem and Appellants' claimed method for reducing or eliminating the incidence of illness in humans caused by *Camplyobacter*.

**F. Rejection of Claims 3, 4, 6, 7, 12, 13 and 17 to 19 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al, Sugita-Konishi et al, Adalsteinsson et al '878, Pimental '489* and *Betz et al '867***

Appellants' analysis of the primary reference, *Tokoro '895*, and secondary references, *Kaspers et al, Sugita-Konishi et al, Adalsteinsson '878, Pimental '489* and *Betz et al '867*, is applicable to this rejection.

Claim 4 has been cancelled. The subject matter of Claim 4 is included in Claim 3. The colony-forming illness-causing immunogen is from the class consisting of *E. coli*, *Listeria*, *Salmonella* and *Campylobacter*.

Claim 3 method includes the drying the entire contents of the eggs and coating a dry feed

carrier with the dried egg antibody. Claims 6, 7, 12 and 13 are dependent claims that include coating a dry feed carrier with the dried egg antibody. The process is not suggested by *Betz et al '867*. The dry feed carrier material is coated with the separated entire contents of the harvested eggs. The dry food carrier material coated with the entire contents of the eggs inhibits the adherence of colony-forming immunogens in the digestive tracts of animals by binding IgY immunoglobulins to the colony-forming immunogens and assisting or helping the binding process with IgM and IgA immunoglobulins. The use of the carrier material helps distribute the entire contents of the eggs in a uniform method in the animal feed. The carrier material coated with the entire contents of the eggs makes it easier for mixing with standard feeds. *Example 21, page 23*. The feed mixed with the carrier material coated with the entire contents of the eggs is supplied to the animals. The carrier material flows with the animal feed down the animals' digestive tracts exposing the IgY, IgM and IgA to colony-forming immunogens therein.

*Betz et al '867* disclose a method of making horse feed by mixing farinaceous material, proteinaceous material with fibrous materials, adding moisture, drying the mixture, and coating the combination with vegetable oil. The fibrous materials are selected from a group consisting of soy hulls, cottonseed hulls, and rice hulls. The fibrous materials provide structural strength of the feed pellets and effect stool normality. The fibrous materials are not coated with egg antibody.

Mixing dry egg powder to animal rations and coating a mixture of animal food with vegetable oil does not suggest to a person skilled in the art to coat a carrier material with IgY antibody as defined in Claims 3, 6, 7, 12 and 13.

In view of the absence of a teaching of the claimed drying of antibody yolk and albumin with a dry feed carrier by *Betz et al '867*, it would not have been obvious to a person skilled in the art to make and use the method claimed in Claims 3, 6, 7, 12 and 13. The Examiner has

failed to show any motivation to combine his references. There is certainly non "clear and particular" showing of motivation to combine the numerous references based on objective evidence of record.

Claim 17 and 18 define Appellants' method as including providing a dry feed carrier material and coating the dry feed material with the separated entire contents of the harvested eggs having IgY immunoglobulins in the yolk and IgM and IgA immunoglobulins in the albumin. The method does not include a separate step of drying the yolk and albumin. The dry feed carrier absorbs moisture from the egg yolk and albumin. The process of using a dry feed carrier to absorb moisture from the yolk and albumin is not present in *Betz et al '867* or the remaining prior art of record.

**G. Rejection of Claims 4, 15 and 16 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al, Adalsteinsson et al '878, Pimental '489* and *Betz et al '867***

Appellants' analysis, *supra*, of the primary reference, *Tokoro '895,* and secondary references, *Kaspers et al, Adalsteinsson et al '878, Pimental '489* and *Betz et al '867*, is applicable to this rejection.

Claim 4 has been cancelled. The subject matter of Claim 4 is included in Claim 3. Claims 15 and 15, dependant on Claim 14, define the added process of drying the antibody containing eggs by coating the dry feed carrier material with the antibody containing contents of the eggs. The comments concerning Claims 17 and 18 are applicable to Claims 15 and 16.

**H. Rejection of Claims 8, 9 and 10 under 35 USC 103(a) over *Tokoro '895* in view of *Kaspers et al, Adalsteinsson et al '878, Pimental '489* and *Betz et al '867***

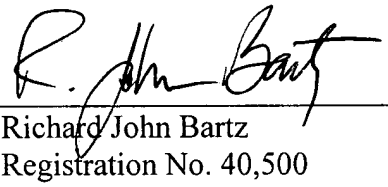
Apellants' analysis, *supra*, of the primary reference, *Tokoro '895*, and secondary references, *Kaspers et al, Adalsteinsson et al '878, Pimental '489* and *Betz et al '867*, is applicable to this rejection.

Claim 8 defines the method for reducing or eliminating the incidence of illnesses in humans caused by *Listeria*. Claims 9 and 10 depend on Claim 8. Claims 9 and 10 include the process of drying the antibody contents of the eggs by coating a dry feed carrier with the antibody-containing contents of the eggs. A separate drying process is not used. The comments concerning Claims 17 and 18 are applicable to Claims 9 and 10. Claim 8 does not include the drying method defined in Claims 9 and 10.

The reversal of the examiner's rejection as to Claims 1, 3 and 5 to 18 is requested.

Respectfully submitted,

PETER NASH ET AL

By 

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## APPENDIX A

1. A method for reducing or eliminating the incidence of illnesses in humans caused by the presence of targeted colony-forming illness-causing immunogens from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter* in meat by inhibiting the ability of the immunogens to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogens to multiply in the rumen or intestinal tracts of the food animals, said method comprising:

A. Inoculating female chickens, in or about to reach their egg laying age, with a targeted colony-forming illnesses-causing immunogen from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter*;

B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the targeted colony-forming illness-causing immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Drying said separated entire contents of said eggs to provide a dried egg antibody product;

F. Mixing the resulting dried egg antibody product substantially uniformly through an animal feed or water; and

G. Supplying the resulting mixed dried egg antibody product and animal feed or water to food animals whereby the IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen, said binding being assisted by the IgM and IgA immunoglobulins to

inhibit ~~to~~ adherence of the targeted colony-forming illness-causing immunogen in the intestinal tract of the food animals thereby reducing or eliminating the incidence of food borne illnesses in humans caused by the presence of the targeted colony-forming illness-causing immunogen in meat.

3. A method for reducing or eliminating the incidence of illnesses in humans caused by the presence of a targeted colony-forming illness-causing immunogen from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter* in meat by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply in the rumen or intestinal tracts of the food animals, said method comprising:

A. Inoculating female chickens, in or about to reach their egg laying age, with a particular targeted colony-forming illnesses-causing immunogen from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter*;

B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the targeted colony-forming illness-causing immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Drying said separated entire contents of said eggs to provide a dried egg antibody product;

F. Providing a dry feed carrier;

G. Coating the dry feed carrier with said egg antibody product;

H. Mixing the resulting dry feed carrier coated with the dried egg antibody product substantially uniformly through an animal feed or water; and

I. Supplying the resulting mixed dry feed carrier coated with dried egg antibody product and animal feed or water to food animals whereby the IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted colony-forming illness-causing immunogen in the intestinal tract of the food animals thereby reducing or eliminating the incidence of food borne illnesses in humans caused by the presence of the targeted colony-forming illness-causing immunogen in meat.

5. A method for reducing or eliminating the incidence of illnesses in humans caused by the presence of a colony-forming illness-causing *E. coli* immunogen in meat by inhibiting the ability of the *E. coli* immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the *E. coli* immunogen to multiply in the rumen or intestinal tracts of the food animals, said method comprising:

A. Inoculating female chickens, in or about to reach their egg laying age, with the illness-causing *E. coli* immunogen;

B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the *E. coli* immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Drying said separated entire contents of said eggs to provide a dried egg antibody product;

F. Mixing the resulting dried egg antibody product substantially uniformly through an animal feed or water; and

G. Supplying the resulting mixed dried egg antibody product and animal feed or water to food animals whereby the IgY immunoglobulins bind to *E. coli* immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the *E. coli* immunogen in the intestinal tract of the food animals thereby reducing or eliminating the incidence of food borne illnesses in humans caused by the presence of *E. coli* immunogen in meat.

6. The method according to Claim 5 including: providing a dry feed carrier, said drying of the antibody-containing contents of said eggs is achieved by coating the dry feed carrier with said separated antibody-containing contents of said eggs.

7. The method of Claim 6 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

8. A method for reducing or eliminating the incidence of illnesses in humans caused by the presence of a colony-forming illness-causing *Listeria* immunogen in meat by inhibiting the ability of the *Listeria* immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the *Listeria* immunogen to multiply in the rumen or intestinal tracts of the food animals, said method comprising:

A. Inoculating female chickens, in or about to reach their egg laying age, with the illness-causing *Listeria* immunogen;

B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the *Listeria* immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Drying said separated entire contents of said eggs to provide a dried egg antibody product;

F. Distributing the resulting dried egg antibody product substantially uniformly through an animal feed or water; and

G. Supplying the resulting mixed dried egg antibody product and animal feed or water to food animals whereby the IgY immunoglobulins bind to the *Listeria* immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the *Listeria* immunogen in the intestinal tract of the food animals thereby reducing or eliminating the incidence of food borne illnesses in humans caused by the presence of *Listeria* immunogen in meat.

9. The method according to Claim 8 including: providing a dry feed carrier, said drying of the antibody-containing contents of said eggs is achieved by coating the dry feed carrier with said separated antibody-containing contents of said eggs.

10. The method of Claim 9 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

11. A method for reducing or eliminating the incidence of illnesses in humans caused by the presence of a colony-forming illness-causing *Salmonella* immunogen in meat by inhibiting the ability of the *Salmonella* immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the *Salmonella* immunogen to multiply in the rumen or intestinal tracts of the food animals, said method comprising:

A. Inoculating female chickens, in or about to reach their egg laying age, with the illness-causing *Salmonella* immunogen;

B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the *Salmonella* immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Drying said separated entire contents of said eggs to provide a dried egg antibody product;

F. Mixing the resulting dried egg antibody product substantially uniformly through an animal feed or water; and

G. Supplying the resulting mixed dried egg antibody product and animal feed or water to food animals whereby the IgY immunoglobulins bind to the *Salmonella* immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the *Salmonella* immunogen in the intestinal tract of the food animals thereby reducing or eliminating the incidence of food borne illnesses in humans caused by the presence of *Salmonella* immunogen in meat.

12. The method according to Claim 11 including: providing a dry feed carrier, said drying of the antibody-containing contents of said eggs is achieved by coating the dry feed carrier with said separated antibody-containing contents of said eggs.

13. The method of Claim 12 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

14. A method for reducing or eliminating the incidence of illnesses in humans caused by the presence of a colony-forming illness-causing *Campylobacter* immunogen in meat by inhibiting the ability of the *Campylobacter* immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the *Campylobacter* immunogen to multiply in the rumen or intestinal tracts of the food animals, said method comprising:

A. Inoculating female chickens, in or about to reach their egg laying age, with the illness-causing *Campylobacter* immunogen;

B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the *Campylobacter* immunogen, said antibody in the eggs including IgY immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Drying said separated entire contents of said eggs to provide a dried egg antibody product;

F. Mixing the resulting dried egg antibody product substantially uniformly through an animal feed or water; and

G. Supplying the resulting mixed dried egg antibody product and animal feed or water to food animals whereby the IgY immunoglobulins bind to the *Campylobacter* immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the *Campylobacter* immunogen in the intestinal tract of the food animals thereby reducing or eliminating the incidence of food borne illnesses in humans caused by the presence of *Campylobacter* immunogen in meat.

15. The method according to Claim 14 including: providing a dry feed carrier, said drying of the antibody-containing contents of said eggs is achieved by coating the dry feed carrier with said separated antibody-containing contents of said eggs.

16. The method of Claim 15 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

17. A method for reducing or eliminating the incidence of illnesses in humans caused by the presence of a targeted colony-forming illness-causing immunogen from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter* in meat by inhibiting the ability of the immunogen to adhere to the rumen or intestinal tracts of food animals to reduce the ability of the immunogen to multiply in the rumen or intestinal tracts of *E. coli, Listeria, Salmonella* and *Campylobacter*, said method comprising:

A. Inoculating female chickens, in or about to reach their egg laying age, with a particular targeted colony-forming illnesses-causing immunogen from the class consisting of *E. coli, Listeria, Salmonella* and *Campylobacter*;

B. Allowing a period of time sufficient to permit the production in the eggs of the chickens of antibody to the targeted immunogen, said antibody in the eggs including IgY

immunoglobulins in the yolks of the eggs and IgM and IgA immunoglobulins in the albumin of the eggs;

C. Harvesting the eggs laid by the chickens;

D. Separating the entire contents of said harvested eggs from the shells;

E. Providing a dry feed carrier material;

F. Coating said dry feed carrier material with the separated entire contents of said harvested eggs;

G. Mixing said carrier material coated with the separated entire contents of said harvested eggs substantially uniformly in animal feed; and

H. Supplying the resulting mixed dry carrier material coated with the separated entire contents of said harvested eggs and animal feed to food animals whereby the IgY immunoglobulins bind to the targeted colony-forming illness-causing immunogen, said binding being assisted by the IgM and IgA immunoglobulins to inhibit adherence of the targeted colony-forming illness-causing immunogen in the rumen or intestinal tracts of the food animals thereby reducing or eliminating the incidence of food borne illnesses in humans caused by the presence of the targeted colony-forming illness-causing immunogen in meat.

18. The method of Claim 17 wherein: providing a dry feed carrier material from a group of materials including soybean hulls, rice hulls, corn, cottonseed hulls, distilled dried grains and beet pulp.

PATENT -- FEE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

| | | |
|---|---|---|
| In Re: Application of PETER NASH ET AL | ) | |
| Serial No.: 10/039,977 | ) | |
| Filed: January 8, 2002 | ) | Group Art Unit 1644 |
| For: IMMUNOGEN ADHERENCE INHIBITOR AND METHOD OF MAKING AND USING SAME | ) | Exr. P. Huynh |
| Case Docket No.: C150.12.3E | ) | |

**LETTER**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22131-1450

Sir:

Enclosed are the original and three (3) copies of Appellants' Brief under 37 CFR 1.192 together with the brief filing fee of $250.

Appellants are individual inventors and claim small entity status.

Respectfully submitted,

PETER NASH ET AL

By _____

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on DECEMBER 27, 2004,
(Date of Deposit)

RICHARD JOHN BARTZ
Name of applicant, assignee, or Registered Rep.

R. John Bartz
Signature

DECEMBER 27, 2004
Date of Signature